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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,138	08/19/2004	Rango Dietrich	26230	1681

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EXAMINER

SILVERMAN, ERIC E

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 09/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/505,138	Applicant(s) DIETRICH ET AL.	
	Examiner Eric E. Silverman, PhD	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8-19-2004</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Receipt is acknowledged of Information Disclosure Statement, filed 10/22/2004.

Claims 1 – 11 are pending in this action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 11 recites "prophylaxis of ... a disease ... preventable by PDE 4 inhibitors". However, the claim does not specify, and the specification provides no guidance, as to what types of diseases are thus preventable. The specification speaks only to diseases that are treatable by PDE 4 inhibitors. Treatment and prevention are not the same.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites "prophylaxis of ... a disease ... preventable by PDE 4 inhibitors". However, the disclosure gives no guidance as to what types of

diseases may be preventable by administration of such compounds. Thus, the claim is merely an invitation for a person of ordinary skill in the art to experiment to determine what diseases could be prevented by the practice of claimed method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 – 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rennard et al., US 20030018071 A1 in combination with Ghebre-Sellassie et al, (US 6,667,362 B1)

Rennard teaches PDE 4 inhibitors whose solubility is slight, of which roflumilast is included (paragraph 0015). Rennard further teaches these as an immediate release tablet, wherein the tablet contains a lubricant (magnesium stearate), and a filler (lactose

monohydrate) (example 4). Examiner notes that roflumilast is the compound of claim 7, and that Rennard therefore meets all requirements regarding solubility and structure in instant claims.

Rennard does not teach the use of poly(vinylpyrrolidone) in the composition.

Ghebre teaches a method of formulating a drug that has slight solubility. This method comprises using poly(vinylpyrrolidone) in the formulation of the drug (see abstract). Ghebre provides Romglizone as a specific example of a drug that may benefit from this formulation (see example 1), but does not limit the drugs that may so benefit, instead saying that almost any drug that has some water solubility may be used (see claim 1 and column 3, lines 7 – 10).

Thus, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use poly(vinylpyrrolidone) in the composition Rennard, the result being the invention of instant claims. Thus, the invention defined by instant claims is prime facie obvious in its entirety. The motivation for combining is provided by Ghebre, who teaches that formulations of drugs that are slightly soluble (such as roflumilast) which include poly(vinylpyrrolidone) offer increased bioavailability of the drug. The expected result would be an instant release tablet of roflumilast with increased bioavailability. Since this is the result is identical to the result disclosed in instant Application, the results in this Application are not unexpected.

Furthermore, since these manipulations are expressly suggested by the prior art, a person of ordinary skill in the art would have a reasonable expectation of success in carrying them out.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 20030212112 A1 discloses formulations of roflumilast in tablet form.

No claims are allowed. No claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 9:00am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eric Silverman, PhD
Art Unit 1615



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